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K050163

SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address & Phone Number: Henke Sass Wolf of America
44 Southbridge Rd.
Dudley, MA 01571

Submission Correspondent: Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, NJ 08822
Attention: Lynette Howard

Classification Name: Endoscope & Accessories
Common / Usual Name: Bariatric Laparoscope
Proprietary Name: Henke Sass Wolf Bariatric Laparoscope

Establishment Registration Number: 1222997

Classification: Class II, Reg. # 876.1500, GCJ Gastroenterology - Urology

Performance Standards: No performance standards have been developed for this device.

Substantial Equivalence:

The Henke Sass Wolf of America Bariatric Laparoscopes are substantially equivalent to the Henke Sass Wolf GmbH - K941967 and the Stryker – K993045 in design, materials, methods of construction and intended use.

The intended use of the devices to which we claim substantial equivalence:

The Henke Sass Wolf of America HSW Laparoscopy Set (K941967) is intended to be used in general laparoscopic surgery. Laparoscopic surgery is a means of performing diagnostic and therapeutic surgical procedures intra-abdominally using equipment that minimizes surgical invasiveness. Rather than creating large incisions to gain access to surgical sites, surgeons view inside the body and operate by using instruments inserted through small skin punctures (inserted through the laparoscope or through another small incision). This includes, but is not limited to such uses as gallbladder and appendix removal, hernia repair, and examination of the abdominal cavity, appendix, gallbladder, and liver.

The Stryker Bariatric Laparoscopes (K993045) are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments. This includes, but is not limited to such uses as gallbladder and appendix removal, hernia repair, gastric bypass, laparoscopic Nissen and examination of the abdominal cavity, appendix, gallbladder and liver.

Bariatric laparoscopes allow surgeons to perform procedures on morbidly obese segments of the patient population.

Testing conducted to assure safety and effectiveness include but is not limited to:

Biological Evaluation of Medical Devices – ISO 10993-1, ISO 10993-5, ISO 10993-12
Electrical Safety Requirements as per IEC 601-2-18 as a type BF or Type CF applied as part of medical electrical equipment.
AAMI / ISO Standards for Sterilization of Medical Devices

Proposed devices have successfully met the requirements of the above.

Description of the new device:

The Henke Sass Wolf of America's Bariatric Laparoscope is identical in terms of materials and modes of construction, optical performance and safety to Henke Sass Wolf GmbH HSW Laparoscopy Set - K941967 and the Stryker – K993045. This Bariatric version is longer (up to 550mm) so that it is capable of performing the same types of procedures on morbidly obese segments of the patient population.

Specifications / Materials:

Diameter	**5mm - 10mm**
Length	**280mm to 550mm**
Direction of View	**0, 30, 45 Degrees**
Field of View	**75 Degrees**
Shaft	**300 Series Stainless Steel**
Body	**Stainless Steel**
Sidearm	**Stainless Steel**
Eyepiece	**P.E.E.K.**
Lenses	**Glass or Sapphire**

Adapters for connection to all conventional light-guides are supplied as standard.

The device is intended to be sterilized prior to use. The Bariatric Laparoscopes are designed to facilitate cleaning and disinfection as were the predicate devices. There is no difference in design and material that would impact the sterilization validation conducted for the HSW predicate device.

Instructions for cleaning and sterilization are included in the instructions for use. Sterilization and disinfection validation for predicate devices included EtO, Steris, and Sterrad is performed to assure an SAL of 10-6 per AAMI / ISO Standards.

Intended Use:

The Henke Sass Wolf of America HSW Bariatric Laparoscope is intended to be used in general laparoscopic surgery. Laparoscopic surgery is a means of performing diagnostic and therapeutic surgical procedures intra-abdominally using equipment that minimizes surgical invasiveness. Rather than creating large incisions to gain access to surgical sites, surgeons view inside the body and operate by using instruments inserted through small skin punctures (inserted through the laparoscope or through another small incision). This includes, but is not limited to such uses as gallbladder and appendix removal, hernia repair, and examination of the abdominal cavity, appendix, gallbladder, and liver.

Bariatric laparoscopes are intended to be used to perform surgical procedures on morbidly obese segments of the patient population.

Caution: Federal (USA) law restricts this device to sale, distribution, and use by, or on the order of, a physician.

Safety and Efficacy Information:

There are no changes in the material used in the manufacturing process, which would affect the Safety and Effectiveness of the proposed device.

The HSW Bariatric Laparoscope does not introduce new issues when compared to its predicate devices or uses. Therefore, the HSW Bariatric Laparoscope is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Henke Sass Wolf of America, Inc.
c/o Ms. Lynette L. Howard
Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, New Jersey 08822

Re: K050163
Trade/Device Name: Henke Sass Wolf Bariatric Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 3, 2005
Received: March 4, 2005

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050163

Device Name: **Henke Sass Wolf Bariatric Laparoscope**

Indications For Use:

The Henke Sass Wolf of America HSW Bariatric Laparoscope is intended to be used in general laparoscopic surgery. Laparoscopic surgery is a means of performing diagnostic and therapeutic surgical procedures intra-abdominally using equipment that minimizes surgical invasiveness. Rather than creating large incisions to gain access to surgical sites, surgeons view inside the body and operate by using instruments inserted through small skin punctures (inserted through the laparoscope or through another small incision). This includes, but is not limited to such uses as gallbladder and appendix removal, hernia repair, and examination of the abdominal cavity, appendix, gallbladder, and liver.

Bariatric laparoscopes are intended to be used to perform surgical procedures on morbidly obese segments of the patient population.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K050163